K001023

SEP 22 2000

510(k) Summary

Submitted by:	JOHNSON & JOHNSON Consumer Companies, Inc. 199 Grandview Road Skillman, New Jersey 08558
Contact Person:	Joseph Kiceina Phone: (908) 874-1216 FAX: (908) 874-1118
Date of Summary Preparation:	March 29, 2000
Proprietary Name:	Not determined
Classification (Common) **Name:**	Combination device, adhesive bandage with OTC drug, has not been classified
Product Code:	
Device Classification:	Combination of adhesive bandage and OTC drug has not been classified

Marketed Device(s) to which Equivalency is Claimed:

BAND-AID® Brand Antibiotic Bandages

Description of Device:

Freedom adhesive bandages have an ointment containing an external analgesic on the pad. The analgesic and its concentration per gram of ointment is: benocaine-200mg. *Freedom* adhesive bandages with its analgesic ointment perform the same function as other adhesive bandages, to cover and protect minor wounds and relieve pain and itch.

Other than the OTC drug component, all other bandage components are like the components found in currently marketed BAND-AID® Brand Sheer Adhesive Bandages. The backing of the proposed bandage will be either polyvinyl chloride film or rayon / nylon woven fabric. A polypropylene non-woven / polypropylene film laminate pad is centered on the backing which is coated with an acrylic adhesive. The ointment may be covered with an optional polyethylene netting.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 22 2000

Mr. Joseph Kiceina
Manager of Regulatory Affairs
Johnson & Johnson Consumer Companies, Incorporated
199 Grandview Road
Skillman, New Jersey 08558-9418

Re: K001023
Trade Name: Band-Aid Brand Pain Relief (Freedom)
Regulatory Class: unclassified
Product Code: FRO
Dated: July 13, 2000
Received: July 17, 2000

Dear Mr. Kiceina:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Runner

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K001023

DEVICE NAME: Band-Aid Brand Pain Relief (Freedom)

INDICATIONS FOR USE:

For the temporary relief of pain and itching associated with minor burns, minor cuts, scrapes, insect bites or minor skin irritations.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Irene Naveau for PXC 9/11/00

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001023